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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re. Application of Thierry-Palmer, et al.
USSN 10/617,254

Art Unite 1651
Ex. Lankford

Filed July 11, 2003

TITLE: METHOD FOR IDENTIFYING SALT-SENSITIVE PERSONS

Prior Art Disclosure Based on European Search

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

Applicant provides herewith documents cited (previously not considered) in the European Patent Office.

The application before the U.S. Patent Office describes and claims a kit for measuring loss of vitamin D binding proteins into urine by assaying for the ability of a sample of urine to bind labeled 25-hydroxyvitamin D₃. The loss of vitamin D binding proteins into urine is an indicator of salt-sensitivity.

General consideration of documents cited:

The kits cited in the patent contain either an antibody to 25-hydroxyvitamin D (25-OHD) or vitamin D binding proteins (DBP) and are designed to measure the concentration of vitamin D metabolites in the sample (most often plasma or serum) to compare with radio labeled 25 hydroxyvitamin D₃ for binding of the DBP or the antibody that is supplied.

Data from the laboratory of the inventor indicate that plasma 25 OHD concentrations reflect vitamin D intake and can not, therefore, be used as a marker for salt-sensitivity.

US 5202266 A (Nakagawa Nobuaki, et al) discloses a radioimmunoassay designed to measure 25 hydroxyvitamin D₃ in a sample. The procedure uses iodine-labeled 25 hydroxyvitamin D₃ in advance over the previously used tritium-labeled 25-hydroxyvitamin D₃ in previous assays. Also included is a protein antibody against 25 hydroxyvitamin D (25-OHD). The 25 OHD in the sample (plasma, for example) competes against the iodine-labeled 25 hydroxyvitamin D₃ for

binding the antibody. Antibody bound iodine labeled 25-hydroxyvitamin D₃ for binding to the antibody. Antibody bound iodine-labeled 25-hydroxyvitamin D₃ is measured. The greater amount of 25-OHD in the sample, the less antibody bound iodine-labeled 25-hydroxyvitamin D₃ is measured. This invention has nothing related to prediction of salt sensitivity.

WP 99/67211 A to Biomedica GMBH discloses an enzyme-linked immunosorbent assay (ELISA) utilizes biotin-streptavidin labeled vitamin D binding protein (DBP) and a peroxidase-containing secondary antibody against DBP to measure 25-OHD and 1,25-dihydroxyvitamin D in a sample. The vitamin D metabolites bind to the DBP and, in a second step, the anti-DBP of the current application and has no use for evaluating salt sensitivity.

WO 02/46746 A to Immunodiagnostic Systems LTD discloses a method for measuring vitamin D metabolites in plasma or serum samples that first utilizes a non-competitive displacement agent to separate vitamin D metabolites from the proteins to which they are bound. This method eliminates the need for extraction of the sample with organic solvents. The vitamin D metabolites in the samples can then be assayed by use of binding proteins (DBP or albumin), as specific antibody, or ELISA.

J. Steroid Biochem Mol. Biol 1998;66:255-261 of Thierry-Palmer, et al. discloses, at page 256, column 2 the methods described for measuring vitamin D metabolites in plasma samples. At page 260, column 2 it is suggested that low plasma 25-OHD concentration might serve as a marker for salt-induced hypertension. Unpublished data in the laboratory has indicated that plasma 25-OHD concentrations reflect vitamin D intake and can not, therefore, be used as an indication of salt-sensitivity.

Clin. Exp. Pharmacol Physiol 200;27:378-83 of Wu, et al suggests a correlation between severity of hypertension and urinary calcium loss and reports markedly lower plasma 25-OH?D concentrations in salt-sensitive rats when compared with salt-resistant rats. They indicate (page 381, column 3, paragraph 3, lines 7-9) that the cause for the salt-induced decrease in plasma 25-OHD in salt-sensitive rats "is not known".


J Nutr 2003;133:187-190 of Thierry-Palmer, et al, teaches that Dahl salt-sensitive rats excrete 25-hydroxyvitamin D into the urine. The authors of this paper are listed as inventors of the application under consideration. This paper was published after submission of the provisional application from which the instant application takes priority.

WO 02/057797 A of Quest Diagnostics provides kits designed to measure vitamin D metabolites. The kits containing a releasing agent to remove vitamin D metabolites from protein in plasma or serum, thus eliminating the need to purify vitamin D metabolites and DBP for a specific antibody for detection of the released vitamin D metabolites. The invention does not address a means for measuring salt sensitivity.

In conclusion, the art cited in the European Patent Office either is not (by reason of effective date) an appropriate reference against the claims of the invention or does not address the methods and kits of the invention claimed in the application under consideration.

If any fees are required in payment for this disclosure, the commissioner is authorized to debit Deposit Account 08-1652 in any additional amounts required to fully pay all fees.

Respectfully submitted,



Glenna Hendricks, Reg. No. 32,535

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/617,254
Filing Date	July 11, 2003
First Named Inventor	Myrtle Thierry-Palmer
Art Unit	1651
Examiner Name	Lankford
Attorney Docket Number	

Sheet

of

Attorney Docket Number

U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO 99/67211 A	12-29-1999	Biomedica GMBH	claims	
		WO 02/46746 A	06-13-2002	Immunodiagnostic Systems	abstract, claims	
		WO 02/057797 A	07-25-2002	Quest Diagnostics, Inc	abstract; claims	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet <input type="text"/> of <input type="text"/>	Application Number	10/617,254
	Filing Date	July 11, 2003
	First Named Inventor	Myrtle Thierry-Palmer
	Art Unit	1651
	Examiner Name	Lankford
	Attorney Docket Number	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		THIERRY-PALMER, M, ET AL: "Plasma 25-hydroxyvitamin D concentrations are inversely -- salt-sensitive rats." J. Steroid Biochem ol. Biol. 1998;66:255-61	
		WU, ET AL: "Regulation of Sodium, Calcium and Vitamin D --" Clin. Exp. Pharmacol Physiol 200/27:378-83	
		THIERRY-PALMER, MYRTLE ET AL., "Dahl salt-sensitive rats excrete--". J. Nutrition 2003;133:187-190	

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Enclosed herewith is a Prior Art Statement relating to art cited in the European case before the European Office. If any fees are due on account of this filing, the commissioner is authorized to debit Deposit Account 08-1652 in any amounts required to fully pay all fees or to credit any amount required to fully pay all fees.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Glenna Hendricks".

Glenna Hendricks, Reg. No. 32,535